



Pilot Study: QuantiFERON-Gold® TB Test at Tripler Army Medical Center

COL Michael Brumage, MC
Chief, Preventive Medicine
Tripler Army Medical Center





QuantiFERON-Gold® TB Test

- BLUF
 1. QuantiFERON-Gold® (QFT-G, a blood test) represents an FDA-approved major advance in Public Health. It can be used in all instances where the current Mantoux tuberculin skin test is used.
 2. Project (funded by MEDCOM on 18 May 06) will do the following:
 - a. Serve as a large pilot study to test the capabilities, limitations, and economic impact of performing QFT-G in a military setting.
 - b. Assess the impact of switching TB testing from nursing services to lab while fully funding lab services to handle the increased workload.
 - c. Collect economic data and technical expertise to allow a smooth follow-on to the next generation test (QFT-G in-tube testing) which eliminates the 12-hour lab processing requirement and is expected to be a test that can be performed in large populations in even remote settings.
 3. This proposal is not a scientific study.





QuantiFERON-Gold® TB Test

- Currently in use by City & County SF for their population
- Being considered by USAF, Lackland AFB for recruits
- Advantages
 - Markedly less subjectivity in interpreting test
 - Improved specificity over Mantoux TST is currently used
 - less productivity loss of soldiers due to single visit
 - reduced lost medical productivity (20%-50% no show rate for 2nd appointment)
 - Reduced false positive rate resulting in reduced lab, radiology and pharmacy cost, and less unnecessary treatment
 - Improves IMR through improved compliance
- Disadvantages
 - Increased laboratory workload
 - Increased individual testing cost
 - 12 hour window to process blood for testing: unsuitable for remote settings





Background

- Current screening method is Mantoux tuberculin skin test (TST)
- Requires individuals to return for 48-72 hours later for evaluation-approx 20-50% noncompliance rate at TAMC
- All positives require further testing and/or treatment
- TSTs subject to misinterpretation: subjectivity- bump on skin
- QuantiFERON® Gold (QFT-G) testing requires one simple blood test
- QFT-G is less affected by BCG vaccination as is TST
- QFT-G approved by the FDA and recommended by Armed Forces Epidemiological Board in all cases where TST currently used
- Hawaii has the highest incidence of TB in the United States-double the US national average





Pilot Proposal

- Conduct one year pilot at Tripler-approx 3,600 tests on health care workers for annual screening and inprocessing personnel
- Fully develop protocols in preparation for larger scale testing with next generation QFT-G in-tube test (QFT-GIT)
- Proof of concept in advance of mandatory redeployment testing in 25th ID soldiers at SRP site in mid-2007 using QFT-GIT (would require additional funding for this in FY 07)
- Improve the screening of re-deployed soldiers: blood must be drawn in any case for serum repository, streamlining operations
- No need for tested soldiers to return for evaluation
- Speeds the SRP process and requires no second visit
- Increases readiness status of the force because of single visit
- Fewer false positives: less unnecessary treatment- advance in care





Cost Benefit

- Total cost for pilot study is \$95,000 (\$26.14 per person) and includes:
 - Equipment
 - Supplies: durable and expendable
 - Reagents and testing kits
 - Training and necessary validation
- Cost per test is \$15 as opposed to current TST cost per test of < \$2.00 not including labor, lost productivity, treating false positives, and cost of non-compliance to follow-up visits
- \$88/person saved on CXR and labs alone for each false positive
- Benefits include:
 - Less manpower intensive (soldiers and staff)
 - Standard of care testing for Soldiers





Conclusion

- QuantiFERON® Gold TB testing is the least subjective and most specific screening procedure available
- Redeploying Soldiers deserve the most advanced screening to prevent unnecessary testing and misdiagnosis
- More costly, but better clinical effectiveness
- Less manpower intensive
- SRP site testing is a legitimate GWOT expense

